

#### § 411.378

fact and provides the identity of the appropriate expert and an estimate of the costs of the expert advice. As indicated in § 411.375(d), the requestor must pay the estimated cost of the expert advice.

(c) Once HCFA has received payment for the estimated cost of the expert advice, HCFA arranges for the expert to provide a prompt review of the issue or issues in question. HCFA considers any additional expenses for the expert advice, beyond the estimated amount, as part of the costs HCFA has incurred in responding to the request, and the responsibility of the requestor, as described in § 411.375(c).

[63 FR 1657, Jan. 9, 1998]

#### § 411.378 Withdrawing a request.

The party requesting an advisory opinion may withdraw the request before HCFA issues a formal advisory opinion. This party must submit the withdrawal in writing to the same address as the request, as indicated in § 411.372(a). Even if the party withdraws the request, the party must pay the costs the Department has expended in processing the request, as discussed in § 411.375. HCFA reserves the right to keep any request for an advisory opinion and any accompanying documents and information, and to use them for any governmental purposes permitted by law.

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#### § 411.379 When HCFA accepts a request.

(a) Upon receiving a request for an advisory opinion, HCFA promptly makes an initial determination of whether the request includes all of the information it will need to process the request.

(b) Within 15 working days of receiving the request, HCFA—

(1) Formally accepts the request for an advisory opinion;

(2) Notifies the requestor about the additional information it needs, or

(3) Declines to formally accept the request.

(c) If the requestor provides the additional information HCFA has requested, or otherwise resubmits the request, HCFA processes the resubmis-

#### 42 CFR Ch. IV (10–1–00 Edition)

sion in accordance with paragraphs (a) and (b) of this section as if it were an initial request for an advisory opinion.

(d) Upon accepting the request, HCFA notifies the requestor by regular U.S. mail of the date that HCFA formally accepted the request.

(e) The 90-day period that HCFA has to issue an advisory opinion set forth in § 411.380(c) does not begin until HCFA has formally accepted the request for an advisory opinion.

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#### § 411.380 When HCFA issues a formal advisory opinion.

(a) HCFA considers an advisory opinion to be issued once it has received payment and once the opinion has been dated, numbered, and signed by an authorized HCFA official.

(b) An advisory opinion contains a description of the material facts known to HCFA that relate to the arrangement that is the subject of the advisory opinion, and states HCFA's opinion about the subject matter of the request based on those facts. If necessary, HCFA includes in the advisory opinion material facts that could be considered confidential information or trade secrets within the meaning of 18 U.S.C. 1095.

(c)(1) HCFA issues an advisory opinion, in accordance with the provisions of this part, within 90 days after it has formally accepted the request for an advisory opinion, or, for requests that HCFA determines, in its discretion, involve complex legal issues or highly complicated fact patterns, within a reasonable time period.

(2) If the 90th day falls on a Saturday, Sunday, or Federal holiday, the time period ends at the close of the first business day following the weekend or holiday;

(3) The 90-day period is suspended from the time HCFA—

(i) Notifies the requestor that the costs have reached or are likely to exceed the triggering amount as described in § 411.375(c)(2) until HCFA receives written notice from the requestor to continue processing the request;

(ii) Requests additional information from the requestor until HCFA receives the additional information;